CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

No.: 500-06-000656-138

(...)

N Bertrand, [redacted];

-and-

C Maheux, [redacted];

Petitioners

vs.

BAYER INC.;

-and-

BAYER OY;

-and-

BAYER PHARMA AG;

Respondents

AMENDED MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE
(Art. 1002 C.C.P. and following)

TO (...) THE HONOURABLE JUSTICE (...) MICHÈLE MONAST OF THE SUPERIOR COURT OF QUÉBEC, (...) APPOINTED TO PRESIDE IN THE PRESENT MATTER, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONERS STATE(...) THE FOLLOWING:

INTRODUCTION:

1. Petitioners wish(...) to institute a class action on behalf of the following Group of which Petitioners (...) are members:

> All residents of Canada (subsidarily in Quebec) (including their estates, executors, personal representatives, dependants and family members), who had the contraceptive device Mirena inserted, which device was manufactured, marketed or distributed by Respondents and/or related companies, or any other Group or Sub-Group to be determined by the Court;

(hereinafter referred to as the "**Class Members**", the "**Class**", the "**Group Members**", the "**Group**", "**Consumer**", "**Patients**" or "**Users**");

2. Respondent Bayer Inc. is a federal corporation with its registered head office located in the City of Toronto, in the Province of Ontario;

3. Respondent Bayer OY is a pharmaceutical company incorporated under the laws of the Republic of Finland, having its principal place of business in Turku, Finland;

4. Respondent Bayer Pharma AG, formerly known as Bayer Schering Pharma AG, and before that known as Schering AG, is a pharmaceutical company incorporated under the laws of the Federal Republic of Germany, having a principal place of business at Berlin, Germany;

5. Respondent Bayer AG is the parent/holding company of all other named Respondents. As such, all of the Bayer Respondents are affiliated with Bayer AG and with one another;

6. At all material times, Respondents were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling and marketing, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena;

7. Mirena is a T-shaped contraceptive device that is inserted inside a woman's uterus by a healthcare provider. It is in a category of devices known as intrauterine systems ("IUSs") or intrauterine devices ("IUDs"). Mirena slowly releases the hormone, levonorgestrel, continuously over a period of five (5) years in order to prevent pregnancy;

8. If continued use is desired after five (5) years, the old system must be removed and a new one inserted;

9. The anticipated means of removing the device is a simple, non-surgical, procedure;

10. Mirena was approved for sale in the United States in December 2000, and subsequently approved for sale in Canada in February 2001;

11. There are risks of serious injury associated with, and caused by, using Mirena. Such injury includes, but is not limited to, migration of the device within the uterus or outside of the uterus into other tissues and organs, sepsis, organ damage, infertility, irregular bleeding and the need for surgical removal of the device ("Gynecological Adverse Events");

12. In Canada, the health risks associated with Mirena are contained within the device's "product monograph", the whole as more fully appears from a copy of the Mirena Product Monograph, communicated herewith as **Exhibit R-1**;

13. The product monograph is a document prepared by a health product's manufacturer. It contains dosage and usage indications, and is intended to provide healthcare professionals and patients with the necessary information for the safe and effective use of a health product;

14. Mirena's product monograph makes no mention of the risk of migration or complications arising out of migration;

15. Migration of Mirena throughout the body is related to uterine perforation. Uterine perforation describes the condition whereby Mirena either partially or completely perforates the uterine wall. Mirena's monograph currently includes a "serious warning and precaution" that uterine perforation may occur; however, perforation is described as an "uncommon" serious side effect;

16. Both perforation and migration can lead to serious complications, which complications are not adequately or at all enumerated in the product monograph. Perforation and migration often require complicated, expensive and painful treatment to correct. If either takes place, Mirena must be removed by a healthcare professional, sometimes by means of surgery;

17. The product monograph makes no mention of the risk that Mirena can migrate to other parts of the body and cause organ damage. This is in contrast with Mirena's U.S. label, which has warned about the risk of migration since as early as 2008;

18. The product monograph and the U.S. label also fail to identify infertility as a possible outcome from perforation and migration;

19. Both the Canadian monograph and the U.S. label for Mirena indicate that perforation can occur "most often" during insertion of the Mirena device. In reality, perforation can occur long after insertion;

20. From the time when it was approved and the date this claim was issued, there have been 201 reports to Health Canada identifying uterine perforation as an adverse reaction associated with Mirena, the whole as more fully appears from a copy of the Health Canada Summary of Reported Adverse Reactions, communicated herewith as **Exhibit R-2**;

21. The monograph continues to describe perforation as an "uncommon" event notwithstanding that a large number of complaints of perforation and migration have been received by Bayer since the product was introduced into the market. Indeed, the volume of these complaints was large enough so as to cause Bayer, at Health Canada's direction, to issue a public communication and a "Dear Healthcare Professional" letter in June 2010 reminding that Bayer continues to receive reports of uterine perforation, the whole as more fully appears from the June 15, 2010 public communication and letter from Bayer to health care professionals, communicated herewith as **Exhibit R-3**, *en liasse*;

22. The Petitioners and other putative class members did not receive the June 2010 public communication or the Dear Healthcare Professional letter;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONERS

23. (...)
24. (...)
25. (...)
26. (...)

PETITIONER N[redacted] BERTRAND

26.1 Petitioner N[redacted] Bertrand (hereinafter "**Petitioner B**") is a healthcare professional, specializing in developing hearing wellness programs;

26.2 On December 8, 2011, Petitioner B consulted her gynaecologist Dr. Jeannine Simon who prescribed and recommended that the Mirena IUD be inserted in her the next day;

26.3 Petitioner B therefore purchased the Mirena IUD at a price of $369.17, the reimbursement of which she claims from Respondents, the whole as more fully appears from a copy of the receipt dated December 8, 2011, communicated herewith as **Exhibit R-6**;

26.4 On December 8, 2011, Petitioner B conducted research on the contraceptive device in question. In this regard, Petitioner B reviewed the Mirena brochure provided to her by Dr. Jeannine Simon (which she no longer has) as well as the Mirena IUD's product monograph in the 2009 Compendium of Pharmaceuticals and Specialties, which Petitioner B had access to in the context of her profession, the whole as more fully appears from a copy of the relevant extracts of Petitioner B's 2009 Compendium of Pharmaceuticals and Specialties, communicated herewith as **Exhibit R-7**;

26.5 The next day, on December 9, 2011, Petitioner B had the Mirena contraceptive device inserted by Dr. Jeannine Simon at the Lakeshore General Hospital, the whole as more fully appears from a copy of the Operation Report dated December 9, 2011, communicated herewith as **Exhibit R-8**;

26.6 Approximately one (1) month after the insertion of the Mirena IUD, in early January 2012, Petitioner B returned to visit Dr. Jeannine Simon for a post-

insertion follow-up appointment. Dr. Jeannine Simon proceeded to physically examine Petitioner B and also ordered X-rays and an ultrasound. Said procedures were completed that same day, following which the doctor sent Petitioner B home without scheduling any further tests or appointments;

26.7 Over the next several months, Petitioner B began experiencing abdominal pains and consulted her doctor, Dr. Jeannine Simon, on at least two (2) occasions. The doctor examined Petitioner B each time but did not recommend the removal of the Mirena device;

26.8 Finally, on March 21, 2013, and on her doctor's orders, Petitioner B underwent medical imaging procedures in order to locate the intrauterine device. Petitioner was told that "despite extensive search, the intrauterine device was not clearly identified" and that the device may be outside of the uterus, the whole as more fully appears from copies of the medical imaging reports, communicated herewith as **Exhibit R-9**;

26.9 Accordingly, Petitioner B's doctor (Dr. Simon) decided that the Mirena IUD would need to be surgically removed;

26.10 On June 20, 2013, Petitioner B underwent surgery (by Dr. Simon), under general anaesthesia, in order to have the Mirena device removed, the whole as more fully appears from a copy of the Operation Report, communicated herewith as **Exhibit R-10**;

26.11 Petitioner B was later told by her doctor that the device was removed through an abdominal incision after it was discovered that the IUD device had migrated, as appears from Exhibit R-10;

26.12 Approximately one (1) week following said surgery, Petitioner B suffered a severe infection and was prescribed antibiotics that left her feeling extremely weak and exhausted;

26.13 To this day, Petitioner B has not fully recovered from the adverse effects of the Mirena IUD and the complications she suffered thereafter (the whole as more detailed above);

26.14 In September 2013, Petitioner B was watching television and saw a commercial for litigation in the United-States involving the Mirena contraceptive devices (Petitioner B does not have a copy of said commercial nor does she recall the name or contact information of the lawyers or law firms involved);

26.15 Petitioner B then conducted a "Google" search in order to learn more about said US proceedings and in order to verify whether similar proceedings were filed in Canada. She then discovered that the present Class Action proceedings had been instituted and were still pending;

26.16 Petitioner B then contacted the undersigned attorneys and expressed her interest to act as Petitioner and eventually as Class Representative in these proceedings;

27. As mentioned above, Petitioner B was not made aware by the Respondents of the risks of Gynecological Adverse Events associated with and caused by the Mirena device;

27.1. Given her experience and training as a health care professional and the fact that Petitioner B's above-detailed research on the Mirena IUD revealed no risk nor any mention of the potential migration of the contraceptive device, it is evident that a lay Class Member / Patient (without said experience and training) would also not have known about the risks of migration of the Mirena device;

27.2 Furthermore, no health care professional, including but not limited to Dr. Jeannine Simon, ever informed Petitioner B of the risk of migration associated with and caused by the Mirena device, the whole further evidencing the Respondents' negligence in their duty to properly warn and inform the Patients;

PETITIONER C[redacted] MAHEUX

27.3 Petitioner C[redacted] Maheux (hereinafter "**Petitioner M**") is a lawyer in good standing with the *Barreau du Québec*;

27.4 Following the birth of her son, Petitioner M consulted her obstetrician, Dr. Ingrid Faullem, who prescribed and recommended that the Mirena IUD be inserted in her for contraceptive purposes;

27.5 In fact, Dr. Faullem strongly recommended the Mirena IUD to Petitioner M, who was breastfeeding, since the doctor indicated that Mirena IUD would not interfere with lactation;

27.6 Petitioner M therefore purchased the Mirena IUD at a price of $369.17, the reimbursement of which she claims from Respondents, the whole as more fully appears from a copy of the receipt dated September 26, 2011, communicated herewith as **Exhibit R-11**;

27.7 Prior to the insertion of the Mirena device, Petitioner M reviewed the Mirena IUD's product monograph and asked Dr. Ingrid Faullem several questions concerning the risks associated with the device and its insertion;

27.8 Dr. Ingrid Faullem explained to Petitioner M that there were several risks associated with the device, namely the risk of perforation (which was only present during insertion and caused by improper insertion), infection and

expulsion. However there was no mention in the product monograph as well as by Dr. Faullem of the risk of migration or of the complications arising from migration. Her doctor confirmed that she had successfully inserted such device in her patients more times than she can count, without complications;

27.9 Accordingly, on September 30, 2011, Petitioner M had the Mirena contraceptive device inserted by Dr. Faullem;

27.10 The doctor's notes from that procedure indicate that it was an easy insertion and that the thread was cut and curved following proper insertion protocol, the whole as more fully appears from a copy of the doctor's notes dated September 30, 2011, communicated herewith as **Exhibit R-12**;

27.11 Following the insertion of the Mirena device, Petitioner M experienced severe abdominal pain for which she quickly contacted Dr. Faullem to set up a follow-up appointment;

27.12 On January 20, 2012, Petitioner was seen by Dr. Faullem who could not locate the thread of the Mirena Device and who therefore sent Petitioner M to undergo an ultrasound in order to locate the contraceptive device, the whole as more fully appears from a copy of the medical notes for January 20, 2012, communicated herewith as **Exhibit R-13**;

27.13 On January 23, 2012, Petitioner M underwent two (2) ultrasounds (external and vaginal) at the *Clinique d'échographie de l'Outaouais*, where she was told that the Mirena IUD was difficult to locate by ultrasound but that there were no signs of perforation or complication, the whole as more fully appears from as copy of the ultrasound report, communicated herewith as **Exhibit R-14**. The R-14 report suggests that an X-ray be performed in order to confirm the location of the IUD;

27.14 On February 17, 2012, and following her doctor's recommendations, Petitioner M went for X-rays at the *Clinique Radiologique de Hull*, where she was told that the Mirena Device was "*présumément en bonne position dans la cavité Intra-utérinne. Pas d'autre anomalie démontrée*", the whole as more fully appears from a copy of the radiology report dated February 17, 2012, communicated herewith as **Exhibit R-15**;

27.15 On February 23, 2012, Petitioner M met with gynaecologist Dr. Jean-Claude Paquet, at his private clinic to asses if, with the help of the images of the X-ray and ultrasound, the Mirena device could be removed manually. After three (3) long and agonizing attempts, with no anaesthesia, Dr. Paquet was unable to remove the device manually and suggested that Petitioner M be seen by a gynaecologist in a hospital setting;

27.16 On March 2, 2012, Dr. Faullem referred Petitioner M to Dr. Poungui at the *Hôpital de Gatineau*, the whole as more fully appears from a copy of Dr. Faullem's clinical notes, communicated herewith as **Exhibit R-16;**

27.17 On April 3, 2012, Dr. Poungui attempted once again to remove the Mirena device manually from Petitioner M but was unfortunately unable to remove the device, the whole as more fully appears from a copy of the medical notes from April 3, 2012, communicated herewith as **Exhibit R-17**;

27.18 After multiple failed attempts to remove the device manually, Petitioner M was told by her doctor that there were no other options but to schedule a surgical intervention for the removal of the IUD;

27.19 On May 10, 2012, Petitioner M underwent surgery, under general anaesthesia, to remove the device and was told that the Mirena device had perforated the uterine wall and had migrated, the whole as more fully appears from the surgery report of May 10, 2012, communicated herewith as

Exhibit R-18, as though recited at length herein;

27.20 Thereafter, Petitioner M had to take a two (2) week convalescence, which caused her a loss of gross annual income of $4,807, which she claims from Respondents;

27.21 Following her long and painful ordeal, Petitioner M conducted a "Google" search in order to see if other women had similar experiences with the Mirena device. She then discovered that the present Class Action proceedings had been instituted and were still pending;

27.22 Petitioner M then contacted the undersigned attorneys and expressed her interest to act as Petitioner and eventually as Class Representative in these proceedings;

27.23 As mentioned above, Petitioner M was not made aware by the Respondents of the risks of Gynecological Adverse Events associated with and caused by Mirena device;

27.24 Furthermore, no health care professional, including but not limited to Dr. Ingrid Faullem, ever informed Petitioner M of the risk of migration associated with and caused by the Mirena device, the whole further evidencing the Respondents' negligence in their duty to properly warn and inform the Patients;

28. Petitioners would not have had Mirena IUD inserted had Respondents properly disclosed the full extent of the risks of Gynecological Adverse Events associated with and caused by the device;

29. At the time the Petitioners used Mirena, none of the device's label, the package insert, the package containing the product, or advertisements

provided adequate warnings that using Mirena carried a risk of experiencing Gynecological Adverse Events including such injury as experienced by the Petitioners;

30. Accordingly, the Respondents have failed to discharge their duty to warn and inform the Petitioners and other putative class members about the risk of Gynecological Adverse Events;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

31. As mentioned hereinabove, Respondents were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling and marketing, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena in Canada;

32. At all material times, Respondents have marketed that Mirena is safe which is not true;

33. Mirena is associated with and causes risks of serious injury. Such injury includes, but is not limited to, infertility, perforation of the uterine walls, migration of the device within the uterus or outside of the uterus into other tissues and organs, organ damage, irregular bleeding and the need for surgical removal of the device;

34. Respondents knew or should have known that Mirena is associated with and causes risks of serious injury;

35. Respondents failed in their obligation to adequately warn medical professionals and Canadian Consumers of these effects;

36. Had the Consumers (or Petitioners) been reasonably informed of the risks inherent to the insertion of Mirena, they would not have inserted it or would have had it removed;

37. Respondents committed a fault by putting a dangerous contraceptive on the market, insufficiently tested according to the norms of the trade and by continuing to market the product despite its risks;

38. Consumers reasonably relied and rely upon the Respondents to ensure that the Mirena was safe;

39. Respondents are liable for the damages suffered by the Petitioners and the Class Members in that Respondents were negligent and/or committed a fault when:

(a) It failed to ensure that Mirena was not dangerous to Consumers and that the device was fit for its intended purpose and use;

(b) It failed to conduct appropriate testing to determine whether and to what extent the use of Mirena poses serious health risks;

(c) It failed to adequately test Mirena in a manner that would fully disclose the serious side effects and the magnitude of the risks associated with its use;

(d) It failed to conduct any or adequate follow-up studies on the efficacy and safety of Mirena;

(e) in the alternative to sub-paragraphs (c) and (d) above, it failed to recognize and/or heed the results of studies Respondents conducted or were conducted by others;

(f) It failed to promptly provide the putative class members and their physicians and health regulators with any or adequate warnings of the inherent risks associated with Mirena;

(g) It failed to provide any or adequate updated and current information to the putative class members and their physicians and health regulators respecting the risks and effects of Mirena as such information became available;

(h) It failed to provide prompt warning of potential risks and adverse side effects associated with Mirena on the product monograph and in the product labeling. More particularly, Respondents, contrary to their marketing campaign, knew that a disproportionally high number of its Mirena products were perforating the uterine wall and harming patients post-insertion. Respondents were aware of many complaints made to the Food and Drug Administration ("FDA") in the U.S. and to Health Canada (Exhibit R-2) regarding the perforation of the uterine wall and migration of their Mirena products from the uterus. The perforation of the uterine wall often results in migration from the uterus and often requires complicated, expensive and/or painful treatment to correct;

(i) Indeed, Respondents deliberately obscured the risks of Gynecological Adverse Events. In March 2009, the FDA sent a warning letter to Bayer, expressing concern that Bayer's sponsored links on internet search engines were misleading because they made representations and/or suggestions about the efficacy of Mirena, but failed to communicate any

risk information, the whole as more fully appears from the March 26, 2009 letter from the FDA to Bayer, communicated herewith as **Exhibit R-4**. The FDA letter warned Bayer that advertisements for drugs and medical devices must include risk information. By omitting important risk information, including the most frequently occurring risks and side effects, the ads misleadingly suggested that Mirena is safer than it really is. Canadian putative class members consumed such ads;

(j) In December 2009, the FDA sent a second warning letter to Bayer due to a promotional program for Mirena. The FDA warned that the program overstates the efficacy of Mirena, presents unsubstantiated claims, minimizes the risks of using Mirena, and includes false or misleading representations regarding Mirena. The FDA also pointed out that, contrary to what Bayer was claiming in that program, many women do not "feel better", the whole as more fully appears from a copy of the December 30, 2009 letter from the FDA to Bayer, communicated herewith as **Exhibit R-5**. Canadian putative class members consumed such ads as well;

(k) It failed to warn the putative class members and their physicians and health regulators about the need for comprehensive regular medical monitoring to ensure the device did not migrate post-insertion and cause perforation, and to ensure that, if migration and/or perforation did occur, that these were detected early;

(l) After receiving actual or constructive notice of migration and post-insertion perforation associated with Mirena, it failed to issue adequate or timely warning, withdraw or recall the device, publicize the problems and

otherwise act properly and in a timely manner to alert the public, putative class members, and their physicians and health regulators of the device's inherent dangers;

(m) It failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the usage of Mirena and the risks associated with the device;

(n) It falsely stated and or implied that Mirena was safe and fit for its intended purpose when it knew or ought to have known that these statements were false;

(o) It failed to cease the manufacture and or distribution of Mirena when it knew or ought to have known that the device caused or could cause significant injury and death;

(p) It failed to instruct its employees properly to monitor and record complaints of adverse effects of Mirena;

(q) It failed to accurately and promptly disclose to Health Canada information relating to increased risks associated with Mirena and to adequately and/or promptly modify the product monograph and product labeling accordingly in a timely manner and/or at all;

(r) It failed to monitor and to initiate a timely review, evaluation, and investigation of reports of adverse events associated with Mirena in Canada and around the world;

(s) It marketed and sold Mirena without disclosing the device's risks when it knew or ought to have known of the adverse events associated with the device's use;

(t) It failed to warn the Petitioners, putative class members, and health professionals that Mirena was not as safe as other available contraceptives;

(u) It failed to warn the Petitioners, putative class members, and health professionals that the risks of adverse events with Mirena are higher than those of other available contraceptives;

(v) It failed to provide any or adequate warning to the health profession and to the Petitioners and putative class members;

(w) It failed to properly investigate cases of adverse events and reactions caused by Mirena;

(x) It falsely understated the risks of Mirena, while at the same time falsely overstating the safety and efficacy of the device;

40. As a direct and proximate result of the Respondents' negligence, the Class Members suffered pain, damages, injuries and risks for which the Respondents are solely liable;

41. Each Member of the Group is entitled to claim damages because of the faults committed by the Respondents, which include but are not limited to the reimbursement of the purchase price for the contraceptives, personal injuries suffered, economic and financial losses (i.e. loss of income and earning capacity), pain and suffering, loss of amenities and enjoyment of life, costs of past and future care and related expenses, such further and other damages, the particulars of which may be proven at the trial on the merits;

42. Moreover, Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said drugs, and their failure to fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from the insertion of Mirena (all detailed hereinabove), subject the Respondents to punitive and/or exemplary damages;

43. In fact, Respondents' above detailed actions qualify its fault as intentional which is a result of wild and foolhardy recklessness in disregard for the rights of the Class Members, with full knowledge of the immediate and natural or at least extremely probable consequences that its action would cause to the Class Members;

44. Respondents' negligence has shown a malicious, oppressive and high-handed conduct that represents a marked departure from ordinary standards of decency. In that event, punitive damages should be awarded to Class Members;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

45. The composition of the Group makes the application of Articles 59 or 67 C.C.P. impractical for the following reasons:

    a. The number of potential Group Members is so numerous that the joinder of all Members is impracticable. While the exact number of Group

Member is unknown to Petitioners at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and their agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Quebec and the rest of Canada;

b. Based on the number of potential Group Members, it is impossible for the Petitioners to identify all potential Group Members and obtain a mandate from each of them. Petitioners (...) do not possess the names and addresses of potential Group Members. However, Petitioners, through the undersigned attorneys, have already been able to compile a list of over 40 Class Members, who have signed up on the undersigned attorneys' website in relation to this Class Action. There are also similar Class Action proceedings having been filed in the Provinces of Ontario, Nova Scotia and Alberta, aside of course from the numerous cases filed in the Unites-States of America. Petitioners reserve their right to amend these proceedings in order to make specific references to the other similar class action proceedings filed in other jurisdictions and/or to file documents or proceedings related thereto;

46. The recourses of the members raise identical, similar or related questions of fact or law, namely;

a. Were Respondents negligent or did they commit fault in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Mirena?

b. Did the Respondents know or should Respondents have known that Mirena posed serious health risks?

c. Did the use of Mirena cause or increase the likelihood of Gynecological Adverse Events in patients?

d. Was Mirena defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Mirena defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of Mirena?

f. Are Respondents liable to pay damages equal to the purchase price of Mirena, or part of the purchase price of Mirena, and if so in what amount?

g. Are Respondents liable to pay damages to the Group Members as a result of their negligence, faults or misrepresentations made to them in manufacturing, marketing, distributing or selling of Mirena or as a result of the use of Mirena?

h. Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?

i. Are the Respondents liable to pay moral damages to the Group Members, and if so in what amount?

j. Are Respondents liable to pay exemplary and/or punitive damages to the Group Members, and if so in what amount?

47. The majority of the issues to be dealt with are issues common to every Group Member;

48. The interests of justice favour that this motion be granted in accordance with its conclusions;

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

49. The action that the Petitioners wish(...) to institute for the benefit of the Members of the Group is an action in damages for product liability;

50. The conclusions that the Petitioners wish(...) to introduce by way of a motion to institute proceedings are:

> **GRANT** Petitioners' (...) action against Respondents;
>
> **CONDEMN** Respondents solidarily to reimburse to Petitioners and the Class Members the purchase price paid, plus interest as well as the additional indemnity;
>
> **CONDEMN** Respondents solidarily to pay an amount in compensatory damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;
>
> **CONDEMN** Respondents to pay an amount in moral damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;
>
> **CONDEMN** Respondents to pay an amount in punitive and/or exemplary damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;
>
> **GRANT** the class action of Petitioners on behalf of all the Members of the Group;
>
> **ORDER** the collective recovery of the above amounts;
>
> **THE WHOLE** with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including experts' fees and publication fees to advise members;

51. Petitioners suggest(...) that this class action be exercised before the Superior Court in the District of Montreal for the following reasons:

a. The only Canadian Respondent, Bayer Inc., has its principal establishment in the District of Montreal;

b. Mirena is sold in the District of Montreal;
c. Petitioner B and Many Group Members are domiciled or work in the District of Montreal;
d. Petitioners' and Respondents' (...) legal counsel practice law in the District of Montreal;

52. Petitioners, who (...) are requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since Petitioners:

a. purchased and had Mirena inserted without being made aware of the health risks associated with the use thereof;
b. suffered damages and injuries from inserting Mirena, which includes the migration of the device and its ultimate surgical removal, the whole as more fully detailed above;
c. understand(...) the nature of the action (*inter alia* Petitioner B considering her training in the medical field and Petitioner M as a Quebec lawyer, the whole as mentioned above) and (...) have the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;
d. are (...) available to dedicate the time necessary for the present action before the Courts of Quebec and to collaborate with Class attorneys in this regard, the whole as already confirmed by their above-mentioned research to discover the filing of the original proceedings herein and their intention to become the Petitioners requesting to be ascribed the status of Class Representatives;
e. are (...) ready and available to manage and direct the present action in the interest of the Class Members that Petitioners wish(...) to represent, and are (...) determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;
f. do (...) not have interests that are antagonistic to those of other members

of the Group;

g. have (...) given the mandate to the undersigned attorneys to obtain all relevant information to the present action, including but not limited to the maintaining of the designated webpage about this case on the undersigned attorneys' website, in order to inform other Class Members and in order for said Class Members to be able to sign-up to receive future notices going forward, and Petitioners intend(...) to keep informed of all developments;

h. are (...), with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

53. The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present Motion;

ASCRIBE the Petitioners the status of representatives of the persons included in the group herein described as:

> All residents of Canada (subsidarily in Quebec) (including their estates, executors, personal representatives, dependants and family members), who had the contraceptive device Mirena inserted, which device was manufactured, marketed or distributed by Respondents and/or related companies, or any other Group or Sub-Group to be determined by the Court;

IDENTIFY the principle questions of fact and law to be treated collectively as the following:

a. Were Respondents negligent or did they commit fault in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Mirena?

b. Did the Respondents know or should Respondents have known that Mirena posed serious health risks?

c. Did the use of Mirena cause or increase the likelihood of Gynecological Adverse Events in patients?

d. Was Mirena defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Mirena defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of Mirena?

f. Are Respondents liable to pay damages equal to the purchase price of Mirena, or part of the purchase price of Mirena, and if so in what amount?

g. Are Respondents liable to pay damages to the Group Members as a result of their negligence, faults or misrepresentations made to them in manufacturing, marketing, distributing or selling of Mirena or as a result of the use of Mirena?

h. Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?

i. Are the Respondents liable to pay moral damages to the Group

Members, and if so in what amount?

j. Are Respondents liable to pay exemplary and/or punitive damages to the Group Members, and if so in what amount?

IDENTIFY the conclusions sought by the action to be instituted as being the following:

GRANT Petitioners' (...) action against Respondents;

CONDEMN Respondents solidarily to reimburse to Petitioners and the Class Members the purchase price paid, plus interest as well as the additional indemnity;

CONDEMN Respondents solidarily to pay an amount in compensatory damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to Petitioners and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

GRANT the class action of Petitioners on behalf of all the Members of the Group;

ORDER the collective recovery of the above amounts;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including experts' fees and publication fees to advise members;

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Members;

ORDER the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P. and pursuant to a further hearing to be held, and **ORDER** Respondents to pay for said publication costs;

THE WHOLE with costs, including all costs related to publication of notices to the Class Members.

MONTREAL, (...) MARCH 4, 2014

LEX GROUP INC.

Lex Group INC.

Per: David Assor

Attorneys for Petitioners

N°.: 500-06-000656-138

SUPERIOR COURT
(CLASS ACTION)

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N[redacted] BERTRAND
-and-
C[redacted] MAHEUX

Petitioners

-vs.-

BAYER INC.

-and-

BAYER OY

- and-
BAYER PHARMA AG

Respondents

AMENDED MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE

ORIGINAL

Me David Assor

LEX GROUP

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